

REMARKS

The undersigned attorney wishes to thank the Examiner and the Examiner's Supervisor for the many courtesies exchanged during the telephonic interview of November 4, 2010.

Claims 10-12 and 14-18 are pending and have been examined on the merits. Claim 10 is amended hereinabove. Support for amended claim 10 can be found in the specification at page 16 (reduced libido), pages 17, 23, 26 and 27 (reduced quality of erections), page 29 (depression of mood) and page 30 (fatigue). No new matter has been added.

Claims 10-12 and 14-18 stand rejected under 35 U.S.C. § 103(a) as being obvious over Cavazza (US Patent No. 4,474,812, hereinafter "Cavazza I"), Cavazza (US Patent No. 6,245,378, hereinafter "Cavazza II") and De Felice (US Patent No. 3,830,931, hereinafter "De Felice") in view of De Simone (US Patent No. 6,037,373, hereinafter "De Simone") and Xiu (US Patent No. 6,399,116, hereinafter "Xiu").

Applicants respectfully traverse the rejection.

The presently claimed invention is directed to a method for treating reduced libido, reduced quality of erections, depression of mood and fatigue caused by andropause by administering to a patient in need thereof a combination of acetyl and propionyl L-carnitine. This combination does not increase the level of testosterone in the blood (*e.g.*, page 19, table 11).

As previously submitted, Cavazza I only provides for novel uses of compositions comprising L-carnitine to improve biochemical and behavioral parameters peculiar to senility (*e.g.*, the abstract). However, Cavazza I is completely silent with regard to the use of propionyl and acetyl L-carnitines to treat the disorders discussed above.

Cavazza II does not correct the deficiencies of Cavazza I because it suffers from the same deficiencies. Specifically, Cavazza II only provides for nutritional supplements comprising

“carnitines” for facilitating the adaptation of skeletal muscles in individuals undergoing programs of strenuous exercise (*e.g.*, col. 1, lines 9-14 and the abstract). Cavazza II, as Cavazza I discussed above, is completely silent with regards to a method to treat the disorders discussed above without increasing the blood level of testosterone as claimed herein.

De Felice as well suffers from the same deficiencies of Cavazza I and Cavazza II. Specifically, De Felice only provides for methods for alleviating congestive heart failure and shock with carnitine (*e.g.*, col. 1, lines 22-24 and 36-42). However, De Felice is also silent with regard to the presently claimed method for treating disorders caused by andropause.

De Simone does not provide the missing links. De Simone only discloses that carnitines are capable of increasing the level of IGF-1 in human biological fluids (*e.g.*, col. 2, lines 45-55). However, De Simone also does not provide any hint of a method for treating disorders caused by andropause by administering carnitines without increasing the blood testosterone level.

Finally, Xiu provides for administration of a preparation comprising *Rhodiola crenulata* to treat a variety of ailments (*e.g.*, col. 1, lines 5-24). However, Xiu describes that *Rhodiola crenulata* does cause an increase in testosterone levels in a host in need thereof (*e.g.*, col. 4, lines 43-46 and col. 5, lines 5-19). Further, Xiu describes a list of preferred compounds, one of which is carnitine (*e.g.*, col. 3, lines 13-30).

Thus, not only Xiu teaches away from the presently claimed invention which comprises the administration of a composition which does not increase testosterone blood levels, but also does not provide any motivation to choose carnitine among all of the other preferred compounds. *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007).

Accordingly, it would not be obvious for one skilled in the art to select carnitine among all of the preferred compounds, especially when Xiu teaches away from the presently claimed

invention.

Accordingly, Applicants assert that the combination of the cited references does not disclose, teach or even suggest the presently claimed method which is not obvious or inherent in the teaching of the combination of the cited references. *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957).

As such, for all of these reasons, it is respectfully submitted that the Examiner's asserted combination of Cavazza I, Cavazza I and De Felice in view of De Simone and Xiu would not have rendered obvious the claimed subject matter to one skilled in the art. Thus, withdrawal of the rejection of claims 10-12 and 14-18 for allegedly being obvious under 35 U.S.C. § 103(a) is respectfully requested.

This response is being filed within the shortened statutory period for response, thus, no fees are believed to be due. If, on the other hand, it is determined that further fees are necessary or any overpayment has been made, the Commissioner is hereby authorized to debit or credit such sum to Deposit Account No. 02-2275.

Pursuant to 37 C.F.R. § 1.136(a), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time of its timely submission as incorporating a petition for extension of time for the appropriate length of time. The fee associated herewith is to be charged to the above-mentioned deposit account.

If this 37 C.F.R. § 1.116 AFTER FINAL AMENDMENT does not result in allowance of the claims, the Examiner is respectfully invited to contact the undersigned by telephone to expedite removal of any remaining impediments.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted

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